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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/744,605

07/27/2001

Marcel Koken

US471

1616

1444

7590

05/23/2006

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/744,605

Applicant(s)

KOKEN ET AL.

Examiner

Karen A. Canella

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 17, 19, 29, 30 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 17, 19, 29, 30 and 34-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

Claims 12, 15, 16, 21, 24-28 and 31-33 have been canceled. Claim 17 and 19 have been amended. Claims 34-38 have been added. Claims 17, 19, 29, 30 and 34-39 are pending and under consideration.

Text of Title 35, U.S. Code, not found in this action, can be found in a prior action.

Claims 17, 19, 29, 30 and 34-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 has been amended to require the death of leukemia or lymphoma cells by a mechanism involving the synergistic interaction of an interferon in combination with any of arsenic trioxide or zVAD or DEVD. Claim 34 requires the treatment of any type of leukemia by a combination of interferon and any of arsenic trioxide or zVAD or DEVD, wherein the combination is synergistic. The originally filed specification states (page 17, lines 26-28),

*In the REF(T) cells, a substantial synergy was found between either alpha interferon and zVAD, or alpha interferon and As2O3.*

There is no other reference to a synergistic effect of the combination. Further, claims 17, 19, 29 and 30 encompass any type of leukemia as well as lymphoma. However, it is noted that neither the specific nor the art provides support for the phenomenon of delocalization of PML away from the nuclear body in a PML-RARalpha fusion protein as a result of a chromosomal translocation for lymphoma or any other type of leukemia beyond APL. The specification states (page 1, line 35 to page 2, line 2) that the

*major consequence of this discovery is that a substance promoting retargeting of the PML protein to the cellular bodies and/or its stabilization is particularly useful for inducing the death of undesirable cells.*

One of skill in the art upon reading the instant specification would have reasonably concluded that only APL which exhibited delocalized expression of PML would respond in a synergistic manner to the combination of interferon with any of As2O3 or zVAD or DEVD because only APL cells would express PML-RARalpha responsible for the delocalization of PML away from the nuclear body. therefore one of skill in the art would have reasonable concluded that the combination of interferon and any of As2O3 or zVAD or DEVD would not be synergistic for inducing cell death in any type of leukemia beyond that of APL; or lymphoma.

The rejection of claims 12, 16-19 and 21 under 35 U.S.C. 103(a) as being unpatentable over He et al (Anticancer Research, 1997, Vol. 17, No. 5C, page 3927, abstract #6) in view of Muller et al (EMBO, Jan 2, 1998, vol. 17, pp. 61-70) and Chelbi-Alix et al (NATO ASI Series H: Cell Biology (1996, Vol. 99 (Tumor Biology), pp. 17-27) is withdrawn in light of the requirement for synergism between interferon and As2O3.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

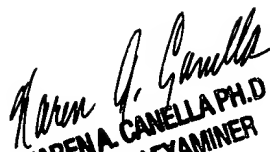
Application/Control Number: 09/744,605

Page 4

Art Unit: 1643

Karen A. Canella, Ph.D.

5/13/2006

  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER